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be 1.0 percent of total payments to ESRD facilities.

[62 FR 43668, Aug. 15, 1997, as amended at 75 FR 49199, Aug. 12, 2010]

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and Scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate CMS-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally consid-

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ered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.200, Reimbursement of OPAs and histocompatibility laboratories;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

(iv) Sections 413.64, Payments to providers, and §§ 413.13, 413.30, 413.35, 413.40, 413.74, and §§ 415.55 through 415.70, § 415.162, and § 415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008]

§ 413.200 Payment of independent organ procurement organizations and histocompatibility laboratories.

(a) *Principle.* Covered services furnished after September 30, 1978 by organ procurement organizations (OPOs) and histocompatibility laboratories in connection with kidney acquisition and transplantation will be reimbursed under the principles for determining reasonable cost contained in this part. Services furnished by free-standing OPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, will be reimbursed by making an interim payment to the transplant hospitals using these services and by making a retroactive adjustment, directly with the OPO or laboratory, based upon a cost report filed by the OPO or laboratory. (The reasonable costs of services furnished by hospital based OPOs or laboratories will be reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* For purposes of this section:

Freestanding refers to an OPO or a histocompatibility laboratory that is not—

(1) Subject to the control of the hospital with respect to the hiring, firing, training, and paying of employees; and

(2) Considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

Histocompatibility laboratory means a laboratory meeting the standards and providing the services for kidneys or other organs set forth in §413.2171(d) of this chapter.

OPO means an organization defined in §486.302 of this chapter.

(c) *Agreements with independent OPOs and laboratories.* (1) Any freestanding OPO or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with CMS under which the OPO or laboratory agrees—

(i) To file a cost report in accordance with §413.24(f) within three months after the end of each fiscal year;

(ii) To permit CMS to designate an contractor to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPO or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPO or laboratory;

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(iv) To pay to CMS amounts that have been paid by CMS to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO or laboratory; and

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an OPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c) (1) and (2) of this section. The initial cost report covers

only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Hospitals eligible to receive Medicare reimbursement for renal transplantation will be paid for the pretransplantation services of a freestanding OPO or histocompatibility laboratory that has an agreement with the Secretary under paragraph (c) of this section, on the basis of an interim rate established by an contractor for that OPO or laboratory.

(2) The interim rate will be based on the average cost per service incurred by an OPO or laboratory, during its previous fiscal year, associated with procuring a kidney for transplantation. This interim rate may be adjusted if necessary for anticipated cost changes. If there is not adequate cost data to determine the initial interim rate, it will be determined according to the OPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made on the basis of the interim rate will be reconciled directly with the OPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all freestanding OPOs and histocompatibility laboratories shall be disseminated to all transplant hospitals and contractors.

(e) *Retroactive adjustment*—(1) *Cost reports.* Information provided in cost reports by freestanding OPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in paragraphs (a) through (e) of §413.24. These cost reports must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services, and any other data necessary to enable the contractor to make a determination of the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by a freestanding OPO or histocompatibility laboratory will be reviewed by the contractor and a new interim reimbursement rate for

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the succeeding fiscal year will be established based upon this review. A retroactive adjustment in the amount paid under the interim rate will be made in accordance with § 413.64(f). If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment will be made directly between that contractor and the OPO or laboratory.

(f) For services furnished on or after April 1, 1988, no payment may be made for services furnished by an OPO that does not meet the requirements of part 486, subpart G of this chapter.

(g) *Appeals.* Any OPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to an contractor hearing, in accordance with the procedures contained in §§ 405.1811 through 405.1833, if the amount in controversy is \$1,000 or more.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§ 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 486.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal contractors. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The

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OPO must submit a request to the contractor for review and approval of these arrangements.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§ 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal contractors.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in § 413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in § 413.217 of this part either directly or under arrangements.

[75 FR 49199, Aug. 12, 2010]